Evidence Table 9. Trials of Case Management for Diabetes Mellitus

| **Author Year (Quality)** | **Study Purpose and/or *A Priori* Hypothesis (if stated)** | **Eligibility Criteria** | **Exclusion Criteria** | **Study Design/Type; Duration of Intervention** | **Demographics: Age (Mean, Median and Range) Gender (% Female) Race and/or Ethnicity  Socioeconomic Status** | **Primary Disease of Population** | **Other Medical Comorbidities and/or Coexisting Mental Illness** |
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| Babamoto 20096  (Fair) | To evaluate the relative effectiveness of an intervention delivered by community health workers as compared to NCM or standard provider care on health measures and clinical indicators among Hispanic persons newly diagnosed with DM-II. | (Recruited from 3 inner-city family health centers in LA between 7/02-7/03) 1. Hispanic/ Latino by self-report 2. Age 18+ 3. Diagnosis of DM-II within 6 months of enrollment | 1. Previous diagnosis of gestational diabetes 2. Previous diabetes care management | Prospective, randomized trial.  Duration: 12 months of recruitment, ~6 months of followup. | Mean age: CHW 51 +/- 12.5 NCM 50 +/- 12.1 Standard 50 +/- 11  % female: CHW 64; NCM 52; Standard 78  % Parent with DM: CHW 45; NCM 55; Standard 35 | DM-II | Only reported comorbidity was hyperlipidemia: CHW 45% NCM 43% Standard 54% |
| Brown 201114  (Poor) | Purpose: To explore the feasibility of adding a nurse case manager to DSME to improve DSME attendance and to increase utilization of other available health care services. Hypothesis: Individuals receiving NCM would have higher intervention attendance and better health outcomes. | Age 35-70 Type-II DM | 1. Prior participation in intervention studies by this group 2. Pregnancy 3. Medical conditions for which changes in diet and physical activity would be contraindicated. | Two cohort, pre-test, post-test comparator group design; CLUSTER RANDOMIZATION  Duration not entirely clear, but authors discuss patient followup with DSME at 3 and 6 months - so presumably at least 6 months. | Mean age: 49.3 +/- 8.4 Intervention 49+/- 7.8; Comparator 49.7 +/- 9.2  % female: 69 Intervention 65%, Comparator 74%  Preferred language Spanish: 61% Intervention 69%; Comparator 51%  Duration DM: 7.1 +/- 6.1 (years) Intervention 7.4 +/- 6.3; Comparator 6.6 +/-5.9  Mean HgA1c Intervention 9.2 +/- 2.7; Comparator 10.6+/- 3  BMI Intervention 34.6+/-7.6; Comparator 32.2+/-5.4 | DM-II | Cholesterol Intervention 171+/-53.4; Comparator 179.6+/-50.2  Triglycerides Intervention 254.4+/-270.5; Comparator 209.4+/-187.8  History of high cholesterol  Intervention 60.4%; Comparator 60%  History of MI Intervention 6.3%; Comparator 8.6%  History HTN Intervention 47.9%; Comparator 54.3% |
| California Medi-Cal Type 2 Diabetes Study Group 200415  Pettitt 200516: (subset analysis to determine risk of retinopathy in type 2 diabetics)  (Fair) | To determine if intensive DM case management using population-directed strategies could improve glycemic control in a Medicaid population of patients with DM-II in which minorities are over-represented. Additionally, to determine if intensive case management could prevent or delay diabetic retinopathy. | 1. Age 18+ 2. DM-II for at least 1 year prior to recruitment 3. HgA1c >7.5% | NR | Randomized controlled trial  Duration: 36 months | Mean age: Intervention 57 +/- 0.9 Comparator 56.9 +/- 1  % female: Intervention 72.6; Comparator 70.9  %African American: Intervention 16.1; Comparator 15.7  % Hispanic: Intervention 39.2; Comparator 38.4  Duration DM: Intervention 10.3 +/- 0.8 years Comparator 12 +/- 0.8 years  HgA1c: Intervention 9.6 +/- 0.1 Comparator 9.7 +/- 0.1  BMI: Intervention 33.1 +/- 0.8 Comparator 31.5 +/- 0.8  SBP: Intervention 136 +/- 2 Comparator 134 +/- 1  LDL: Intervention 129.8 +/- 3.2 Comparator 130.1 +/- 3.6 | DM-II | Intervention 171+/-53.4; Comparator 179.6+/-50.2 |
| Ishani 201142  (Good) | To determine whether nurse case management could effectively improve simultaneous rates of control for hypertension, hyperglycemia, and hyperlipidemia compared with usual care among veterans with diabetes. | Diabetic patients with1 or more: blood pressure (BP) > 140/90 mmHg; hemoglobin A1c (HbA1c)> 9.0%; Low density lipoprotein (LDL) > 100 mg/dL; consented to randomization | Life expectancy of less than 1 year; severe mental health condition or active substance abuse; pregnant or planning on becoming pregnant; living in an assisted living facility; unable to give consent. | Randomized trial.  12 months | N=556  Intervention group:  N=278  Age: 65  Gender: 0.4% female  Race: 93% white, 5% black, 1% other  Usual care group:  N=278  Age: 66  Gender: 2.5% female  Race: 93% white, 4% black, 2% other | Diabetes: with hypertension, hyperglycemia and hyperlipidemia | 1) CHF, neuropathy, stroke, retinopathy, current smokers. 2) NR |
| Gary 200333  (Fair) | To determine whether multi-faceted, culturally sensitive primary care-based behavioral interventions could improve measures of DM control. | 1. Age 35-75 2. African-American ancestry 3. DM-II 4. Live in East Baltimore (by zip code)  5. Received primary care in the year prior at either Johns Hopkins Outpatient Center or the East Baltimore Center for primary care. | 1. Have a comorbid illness which was felt to likely limit lifespan to <4 years (ex: cancer, AIDS)  2. Have end-stage diabetes complications (dialysis, renal transplant, blindness, or LE amputation) | Randomized controlled trial  Enrollment between 4/95-2/97 with 2 years of followup | Mean age:  Usual 57+/- 8; NCM 59+/-11 CHW 59+/-9; NCM/CHW 60+/-7  % Female: Usual 74; NCM 76; CHW 78; NCM/CHW 78  Duration DM (years):  Usual 9+/- 8; NCM 8+/-8 CHW 8+/-8; NCM/CHW 12+/-8  Uses BP meds (%):  Usual 62; NCM 84; CHW 68; NCM/CHW 78  Uses cholesterol meds (%): Usual 18; NCM 18; CHW 22; NCM/CHW 25  Mean BMI:  Usual 34+/- 8; NCM 33+/-8 CHW 33+/-5; NCM/CHW 33+/-7  Mean HgA1c:  Usual 8.5+/- 2; NCM 8.8+/-2.2 CHW 8.4+/-2;  NCM/CHW 8.6+/-1.9 | DM-II |  |
| Gary 200434 Gary 200535 Gary 200936  (Fair) | To determine the effectiveness and cost-effectiveness of primary care and community-oriented interventions in managing HgbA1c, BP, lipids, and reducing ED and hospitalization visits over 2 years. | Patients were initially identified through the managed care organization database, using the following criteria:  1. Age ≥25 years 2. African-American 3. Diagnosis c DM (by ICD-9)   Patients were then screened by telephone to confirm eligibility criteria:  1. DM-II 2. African-American 3. Living in inner-city Baltimore 4. Receiving care at one of 6 included clinic sites 5. Member of managed care organization or included fee-for-service plans 6. Able to provide contact info for 2 family members not living in the home 7. No current enrollment in the managed care organizations other disease management programs. | 1. Have significant comorbid condition(s) likely to lead to death within 3-5 years (ex: cancer, AIDS, ESRD, active TB, Alzheimer’s, CHF - all by ICD-9) 2. Unable or unwilling to give informed consent 3. Unable to complete baseline assessment 4. Likely to move from Baltimore City in the next 24 months 5. Have severe psychiatric condition that would limit participation in the intervention (ex: schizophrenia) | Randomized controlled trial  Enrolled between Oct 2000-June 2002 and followed up for 30 months | Mean age: Minimal intervention: 56.3+/-10.8 Intensive intervention: 58.8+/-11.3 % Female: Minimal intervention: 74 Intensive intervention: 72.1  Tobacco use current:  Minimal intervention: 27.1% Intensive intervention: 32%  BMI:  Minimal intervention: 34.9+/-8.6 Intensive intervention: 34+/-8.2  Mean HgA1c:  Minimal intervention: 8+/-2.2 Intensive intervention: 7.9+/-2.2  Mean SBP:  Minimal intervention: 137+/-20 Intensive intervention: 137+/-21  Mean DBP:  Minimal intervention: 80+/-11 Intensive intervention: 80+/-11  Mean HDL:  Minimal intervention: 51.3+/-15 Intensive intervention: 51.1+/-14.9 | DM-II | Triglycerides |
| Krein 200447  (Fair) | To evaluate the effects of a collaborative CM intervention for patients with poorly controlled T2 diabetes on glycemic control, intermediate cardiovascular outcomes, satisfaction with care, and resource utilization.  Hypothesized that case managers would facilitate more timely and appropriate changes in medication treatment, prompt detection of potential problems, and better patient self management. | Identified potential study subjects had at least one prescription for an oral hypoglycemic agent, insulin, or blood glucose monitoring supplies filled in the previous 12 months. Most recent HbA1C level was 8.5% (within the last year) and had a general medicine clinic visit scheduled between May 1999 and January 2000. During screening visit, patients were eligible if HbA1C >7.5%. | Persons <18 years, never diagnosed with diabetes or before the age of 30 years; no telephone; did not speak English; were not competent for interview; reported primary source of diabetes care outside the VA; current treatment for cancer (other than nonmelanoma skin cancer); had kidney failure, symptomatic heart failure, liver disease, or blindness; spent winter at another residence or planned to move. | Randomized trial Duration: 18 months | Age: 61 years of age 97% Men 51% White | Diabetes | Intervention 254.4+/-270.5; Comparator 209.4+/-187.8 |
| Shea  200298 Shea 2006158 Trief  2006102 Trief  2007103 Shea  200799 Shea  2009100  Palmas 2010101  (Fair) | Hypothesis: A telemedicine intervention will improve outcomes among Diabetics in medically underserved areas via 1) more rapid behavior changes, 2) changes in treatment regimen, and 3) more rapid achievement of glucose and BP control. | Patients must:  -be age 55+ -be a current Medicare beneficiary -have DM -live in a federally designated medically underserved area (MUA) or health professional shortage area (HPSA) | Moderate or severe cognitive impairment  Severe impairments in areas that would preclude ability to utilize telemedical intervention including: -vision  -mobility  -fine motor coordination  -hearing  Severe comorbid conditions (likely to result in death/disability during study)  No free electrical outlet  Spends more than 3 months at location other than home | Randomized controlled trial  Randomized 1:1  Randomized within clusters defined by PCP panels  Duration: 2 years by original methods | Mean age 71 in both usual care and intervention groups  36.5% men and 37.9% men in intervention and usual care groups respectively  15.3% and 14.5% Black in intervention and usual care respectively  35.8% and 34.6% Hispanic in intervention and usual care respectively  ≥13 years education in 16.1% and 17.5% in intervention and usual care respectively  Annual household income of <$10,000 in 50.8% and 47.8% in intervention and usual care respectively | Diabetes  DM duration ≥15 years in 30.8% and 32.2% in intervention and usual care respectively  DM management with insulin alone in 14.5% and 14.4% in intervention and usual care respectively  Mean HgbA1c of 7.36 and 7.40 in intervention and usual care respectively |  |
| Wolf 2004111 (ICAN) Wolf 2007112  (Good) | The objective was to compare the efficacy of lifestyle case management to usual care given in the primary care setting measured by clinical, HRQOL, and economic outcomes. Hypothesized that a modestly priced, RD-led case management approach to lifestyle change would be more effective than usual medical care for patients with obesity and T2 Diabetes. | > 20 years of age, T2 diabetics confirmed by a physician, diabetes medication use, body mass index of >27, ability to comprehend English, and primary health insurance is Southern Health Services health plan | Pregnancy, cognitive limitations, or other medical reasons preventing diet or exercise modifications. | Randomized trial  12 months | Age: Mean=53 years 60% Female 80% White SES: NR | Obese, T2 diabetics | History of MI |

| **Author Year (Quality)** | **Describe Factors of Complex Care Needs** | **Payer/Insurance Carrier** | **Managed Care (Yes/No)** | **Characteristics of the Case Manager** | **Describe Case Management Intervention** | **Describe Preintervention Training** | **Did case manager have the ability to adjust medications?** |
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| Babamoto 20096  (Fair) | % less than 6th grade education: CHW 67; NCM 58; Standard 57  % income less than $25K/year: CHW 55; NCM 50; Standard 56 | NR | No | The NCM was described as being a registered nurse with "linguistic competence" (presumably in Spanish).   No information on education or experience reported. | NCMs interacted with patients in clinic.  NCMs saw patients monthly and as needed. They also performed followup calls with patients as needed.  NCMs followed a "standardized clinic protocol for MD education and monitoring based on ADA clinical recommendations."  NCM responsibilities included patient assessment, development of treatment plan incorporating provider treatment, coordination and referral of community resources, and participation in multi-disc conferences to discuss patient status. | NR | NR |
| Brown 201114  (Poor) | 1. Rural community 2. One of the poorest counties in the United States | NR | NR | NCM was certified as a DM educator and had been an intervention team member with this group prior to this study. | Goal of NCM was to provide individualized guidance.  1. Contact patients at least 5 times (including appointments, telephone calls, home visits)  2. NCMs also attended weekly DSME group sessions  During interactions with patients, NCM was to provide additional info and answer to questions on DM self-management, as well as to provide individualized health guidance and assistance in overcoming cultural and environmental barriers to improving health. NCM also to provide enhanced coordination of health care and communication with physicians and other providers. | NR | NR |
| California Medi-Cal Type 2 Diabetes Study Group 200415  Pettitt 200516: (subset analysis to determine risk of retinopathy in type 2 diabetics)  (Fair) | Patients were recruited from three clinical sites in three counties, all of which served racial/ethnic minorities, and low-income Medicare populations (Medi-Cal) in California.  Education level was relatively poor in these populations, with approximately 40% in each group having an educational level of 8th grade or less.   % education beyond 12th grade: Intervention 20.8; Comparator 19.4  % education 12th grade: Intervention 16.3; Comparator 23.6  % education 9-11th grade: Intervention 21.9; Comparator 17.6  % education 8th grade or less: Intervention 41; Comparator 39.4 | Medicaid | One of the three recruitment sites was part of a county-wide managed care plan for Medi-Cal recipients.  Also, one of the other two sites recruited patients from hospitals and outlying clinic and those patients could be fee for service or part of a managed care plan. | Not entirely clear, but it seems per the study that case managers can be either registered nurses or registered dietitians. No other information on education or experience is provided. | Case managers used evidence-based practice guidelines and algorithms for medicine and insulin adjustment in collaboration with the primary care providers.   Case mangers specifically identified patient barriers to care and then individualized treatment and education strategies to address these barriers.   Case managers followed a study protocol which included basic guidelines for glucose and medication management for DM as well as HTN and dyslipidemia. | NR | NR (suspect "no" as the CMs worked in conjunction with primary care providers). |
| Ishani 201142  (Good) | Patients were diabetic with poorly controlled risk factors | NR | NR | Nurse case managers | After the initial study visit, case manger and patient established lifestyle modification goals (weight loss, dietary changes, physical activity and smoking cessation, as appropriate) and developed personal action plans. All patients provided with validated home blood pressure monitor and instructions. | NR | Yes. Case manager reviewed diabetes, blood pressure and lipid medications and made adjustments to those medications according to protocols established for the study. |
| Gary 200333  (Fair) | Included only African-Americans in East Baltimore.  Years of education (Mean):  Usual 10+/-3; NCM 10+/-2 CHW 9+/-3; NCM/CHW 10+/-3  Percent yearly income ≤$7500: Usual 44; NCM 42; CHW 61; NCM/CHW 43  Percent receiving medical assistance:  Usual 50; NCM 34; CHW 46; NCM/CHW 36 | NR | NR | Registered nurse with bachelors in training to be a certified diabetes educator.   Years of experience NR. | The NCM coordinated patient care using ADA practice guidelines. NCM provided patient care, management, education, counseling, followup, referrals, and physician feedback. Regimen changes were implemented under physician's orders. | NR | No. Regimen changes were implemented under physician's orders. |
| Gary 200434 Gary 200535 Gary 200936  (Fair) | Urban, African-American  Annual income <$7500: MI: 35.5% II: 33.5%  Education (years): MI: 11.5 +/-2.8 II: 11.5+/-2.5  Unemployed: MI: 4.4% II: 4.8%  Per Gary 2005, poor glycemic control and poor BP control were present in 43% and 72% "respectively" (can't tell which group has which by this statement). | Either managed care or fee-for-service | Yes (some) | Registered nurse with bachelor's degree and "relevant case management experience."   Years of experience not specified. | The intensive intervention arm included NCM and CHW collaborative involvement.  The NCM specifically trains and supervises CHWs, oversees the baseline assessment and plan formation for each patient, prompts physicians about sub-optimal care patterns, and is involved in insulin titration.   The CHWs are African-American women familiar with the setting and without prior health care training. They have a high-school education. They also participated in a 6 week training process. CHWs participate in the intake assessment and plan formation, identify non-medical barriers (ex: illiteracy) and work to find solutions to those barriers. Some visits in project office or by phone, some in patient's home, some in community. | 6 weeks training process.  Gary et al 2009 further describes the 6 weeks of training as having 6 phases including guidelines, practical info, patient self-management education, home-based assessment and education, field experience, skill reinforcement, and maintenance and quality control. | Unclear |
| Krein 200447  (Fair) | Average length of diabetes onset= 11 years; 45% if participants rated health as poor or fair (see previous cell, average number of comorbidities= 4) | 100% VA; 60% had other insurance besides VA | Yes, VA | NP case manager | Case managers were allowed to schedule followups according to individual patient needs (e.g., someone newly started on a medication; encouraged patient self-management (e.g., diet and exercise); provided reminders for recommended screenings/tests; help with appointment scheduling; monitor home glucose and blood pressure levels; and identified and initiate medication and dose changes as needed. To facilitate treatment changes, medication treatment algorithms were used, modified to correspond with the National VA Diabetes Guidelines. Providers were notified by internal e-mail if a medicine change was recommended and could opt to have the case manager make the adjustment or to address the issue directly. | 2-day training for case managers included instruction on collaborative goal setting, with case examples and role-playing used to familiarize them with the treatment algorithms. | Yes |
| Shea 200298 Shea 2006158 Trief 2006102 Trief 2007103 Shea 200799 Shea 2009100  Palmas 2010101  (Fair) | Older (age 55+)  Significant % with annual household income <$10,000 (50.8% and 47.8% in intervention and usual care respectively) | Medicare | No | Described only as "nurse care manager." | Video-conference between patient and NCM every 2 weeks and as needed -followup CBGs and BPs remotely via telehealth system discussed with endocrinology if medication adjustment felt needed (after which recommendation made to PCP) -resource referral for individualized patient needs | Nurse care manager -trained in diabetes management -trained in use of computer-based case management tools | Not clearly stated, but believe "no." Stated that NCM discussed care with endocrinologist, and if treatment recommendations then message was sent to primary care provider. |
| Wolf 2004111 (ICAN) Wolf 2007112  (Good) | 1) Average of 7 years with diagnosis of diabetes  2) Average body mass index=37.5 3) Average waist circumference=117 cm 4) Average of 2.6 other conditions besides diabetes 5) Average of 6 meds per day | Southern Health Services medical plan | Yes, Southern Health Services | Registered Dietician | Overall: One RD CM met with participants individually, in groups, and by phone for assessment, goal setting, education, and referrals to community resources.  Clinical care: RD CM reviewed lab results and discussed patient-care issues with physicians when appropriate.  Individual sessions: occurred 6 times throughout the year (total= 4 hours). Followup visits reassessed if goals met and if not, discussed ways to overcome barriers; goals were reset. Monthly calls: provide support. Participants were given the LEARN (Lifestyle, Exercise, Attitudes, Relationships, Nutrition) manual. | NR | No |

| **Author Year (Quality)** | **Primary Location of Case Manager** | **Primary Mode of Case Manager Contact with Patient** | **Caseload** | **Frequency of Visits and Phone Calls** | **Location of Face: Face Time** | **Planning and Assessment** | **Patient Education** | **Self-Management Support** | **Coordination of Services** |
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| Babamoto 20096  (Fair) | Primary care clinic | Primarily in-person appointments (monthly and as needed), but also followup calls as needed. Frequency of followup calls is not reported in results. | 53 patients per NCM  \*\*Note, this refers to 53 patients with DM. These same NCMs were also monitoring patients with other diseases, such as asthma.\*\* | Monthly in-person followup and as needed.  Telephone calls were as needed. Actual frequency experienced was NR. | Primary are clinic. | Only description provided is that "patient assessment and development of a treatment plan" were part of the NCM's responsibilities. | All patients, regardless of study group, received a packet of diabetes education materials (in Spanish and English and tailored for local Hispanic population) during the initial study visit. | NR | One of the NCM responsibilities is listed as "coordination and referral to community resources" - but no additional information is provided. |
| Brown 201114  (Poor) | NR | Mixture of appointments, telephone calls, and home visits | NR (number of NCMs is unclear, but there were 48 individuals in the "intervention" group.) | NR (goal for 5 times total; study period ~6 months) | Clinic visits or home visits | NR | Patient education as part of both comparator and intervention groups. 8 weeks consecutive curriculum followed by support group sessions at 3 and 6 months. | As per previous description, NCMs to provide individualized health guidance. Additional information on this intervention not reported. | Not specifically reported, although authors note that NCM is hoped to enhance coordination of health care and communication with providers. |
| California Medi-Cal Type 2 Diabetes Study Group 200415  Pettitt 200516: (subset analysis to determine risk of retinopathy in type 2 diabetics)  (Fair) | Primary care clinic | Unclear. Study reports that "interactions" between patients and CMs occurred in-person at clinic site and via telephone between visits as needed. | NR | NR | Primary care clinic | "Study staff" (presumably CMs) met with patients "at study entry and exit to assess overall health status, glycemic control, DM self-care behaviors, and presence of DM-related complications." Presumably, the individualized treatment and education strategies were formed at that time - but that is not explicitly stated. | Education strategies are mentioned as one facet of the CM intervention, but no specifics are provided. More detail on CM interventions in table 2 mentions education specifically with regard to nutrition. | Not specifically reported but patient goals are mentioned in Table 2 with regards to nutrition education. | NR |
| Ishani 201142  (Good) | VA hospital | Initial in person visits followed by phone calls | NR | Goal was for case managers to contact patients every 2 weeks initially and for the frequency of contact to decrease as patient achieved home blood pressure and glucose goals.  Median of 15 phone calls.  Median of 3 visits in both groups, p=0.96 | VA hospital | As part of intervention, lifestyle modification goals were established and personal action plans were developed for each patient. | NR | Patients monitored blood pressure, HbA1c and LDL | Registered dietician presented information on dietary choices for diabetes and hypertension including carbohydrate counting, label reading, and the Dietary Approaches to Stop Hypertension (DASH) low-sodium diet. |
| Gary 200333  (Fair) | Clinic | Goal was for three 45-minute face-to-face contacts a year or telephone contacts. Face-to-face was preferred, but telephone was supplemented as needed. | NR | Goal was for three 45-minute face-to-face contacts a year or telephone contacts. | Goal was for three 45-minute face-to-face contacts a year or telephone contacts. Face-to-face contact was preferential, but telephone contact was substituted in patients missed their in-person appointments. In-person contact occurred in clinic.  25% in the NCM-alone group received at least 3 visits. 50% received at least one telephone intervention. | NCM determined needs of patients through baseline assessment. Patients were asked to prioritize three domains related to their DM care for initial attention. | Education is listed as part of NCM's interventions, but no additional information is provided. | NR | Summaries of intervention visits were provided to primary care providers. |
| Gary 200434 Gary 200535 Gary 200936  (Fair) | Primary care clinic appointment | Not entirely clear, but seems primary NCM contact is through clinic appointment. | 1:269. N = 269 in the intensive intervention arm.  Per Gary et al 2005, there was one NCM. | NCM conducts (minimum) 1 face-to-face clinic visit with each patient each year.  CHW has at least 3 contacts with each patient annually. | NCM: face-to-face time occurs in clinic.   CHW: Some visits in project office or by phone, some in patient's home, and some in community. | Plan is formed by NCM with input from CHW at initial baseline assessment. | Patients in the intensive intervention group received DM-specific education (pamphlets, newsletters) via the mail.   In addition, Gary 2009 specified that both NCMs and CHWs utilized clinical algorithms and interactive action plans to help direct education and followup for patients. | NR | At the end of the baseline assessment and as needed, a written summary is sent to each patient's primary care provider. |
| Krein 200447  (Fair) | VA Clinic | Face to face visits, and followup phone calls | 120/case manager (60 patients per 20 hour week case manager) | 3 visits per year, followup calls as needed | Not clearly stated. | Yes | Ongoing | Yes | Yes, with primary care via summary statements and direct discussions. |
| Shea 200298 Shea 2006158 Trief  2006102 Trief  2007103 Shea  200799 Shea 2009100  Palmas 2010101  (Fair) | 2 locations (to accommodate urban and rural population components)  -Berrie Diabetes Center at Columbia University -Joslin Diabetes Center at SUNy Upstate Medical University in Syracuse | Telemedicine videoconference. | 1 NCM for 200 subjects | Not entirely clear.  Shea et al, 2002 implied NCM contact with patient every 2 weeks and as needed (pg 52)   Trief et al, 2007 reported that videoconference occurred every 4-6 weeks routinely, and every 2 weeks for "significant need."   Trief et al 2006 reported that, over the first year, mean home televisits was 28.3 +/- 15.2 (median 28)   In addition, a physical exam and in-person survey was completed at baseline and at 1 year. Examiners were NOT NCMs and were blinded to patient's intervention vs. usual care status. | Not clearly stated, but I believe zero. Two exams were performed (baseline and 1 year), but these exams were NOT performed by NCMs. | Not clearly stated.  Trief et al, 20007 noted that role of NCMs via videoconference was to educate patients, facilitate goal-setting/self-management, and discuss concerns.   Shea et al, 2009 reported that the goal for NCM interventions were based on clinical practice guidelines. (pg 447) | Shea et al, 2002 stated that education and information are available in "small pieces" via the project Web site. "NCMs actively invite and coach patients to use these information resources." | Not specifically reported | NCMs assess patients via telemedicine. If intervention or changes are felt to be needed, NCMs may d/w endocrinologist and make recommendations to PCP. |
| Wolf 2004111 (ICAN) Wolf 2007112  (Good) | Clinic | Sessions with RD and monthly telephone calls. | All participants in intervention group (n=72). | Unclear about study visits; monthly followup calls. | Six times per year, a total of four hours. | Yes, over phone | Participants attended six, 1-hour small group (10 or more people per group) sessions designed to educate subjects about diet and physical activity to improve glucose control and weight loss. | NR | Yes, but unclear |

| **Author Year (Quality)** | **Medical Monitoring** | **Medication Adjustment** | **Integrated within Primary Care** | **Health Information Technology** | **Others** | **Comparator** | **Patient Health Outcomes Included** |
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| Babamoto 20096  (Fair) | HgA1c and BMI were measured at baseline and 6 months. | NR | Yes - NCM's saw patients in primary care clinic and participated in multi-disc meetings to discuss patient status. | NR |  | Two comparators:  Standard provider care: standardized clinical care by physicians and NPs.  CHW care: CHWs were recruited from the community if they were bilingual and had DM or had experienced it through a family member or friend. Each CHW saw between 1-35 patients (3 were utilized full-time). CHWs were required to have high school degree or GED; they were paid clinical staff. Each CHW received a formal 6-week training program. The CHWs conducted individual educational sessions based on ADA standards (conducted with participants and their families). CHWs made "routine" followup calls to monitor progress and assist in problem solving and barrier identification. CHWs utilized program education materials based on a standardized curriculum. | 1. Self-reported quality of health 2. 2+ servings of fruit a day 3. 2+ servings vegetables a day 4. Exercise 3+ times a week 5. Mean HgA1c 6. Mean BMI |
| Brown 201114  (Poor) | Measured at baseline, 3, and 6 months:  1. HgA1c 2. Fasting blood glucose 3. Lipids 4. Blood pressure 5. DM-related knowledge 6. Health behaviors (physical activity, dietary intake, glucose monitoring)  7. BMI | NR | Setting not clearly reported | NR |  | Comparison was between DSME alone vs. DSME + NCM. Education intervention of DSME described previously. | HgA1c BMI Fasting blood glucose |
| California Medi-Cal Type 2 Diabetes Study Group 200415  Pettitt 200516: (subset analysis to determine risk of retinopathy in type 2 diabetics)  (Fair) | In the intervention group, HgA1c was measured quarterly. In the usual care group, the HgA1c was measured every 6 months. | NR (suspect "no" as the CMs worked in conjunction with primary care providers). | Yes (already described) | NR |  | Usual care Included: HgA1c every 6 months and presumably usual MD appointments (although not specifically reported) | Primary outcome: changes in glycemic control (measured by change in HgA1c)   Secondary outcomes:  1. weight 2. BMI 3. BP 4. lipids  Post-hoc: risk of developing retinopathy |
| Ishani 201142  (Good) | During telephone contacts the case manager reviewed the following: self-monitoring values for blood glucose and blood pressure, difficulties experienced in measuring home blood glucose or blood pressure progress toward achieving lifestyle modification goals and any adverse events associated with therapy. | Yes, Case manager reviewed diabetes, blood pressure and lipid medications and made adjustments to those medications according to protocols established for the study. | Primary care provider notified of any medication changed using the electronic medical record system, for providers outside the VA medical system, letter sent informing them of medication changes. | NR | NR | Usual Care: patients asked to continue managing diabetes, blood pressure and lipids under the direction of own primary care provider. | Percentage of patients with control of all three cardiovascular risk factors, defined as: BP < 130/80 mmHg, LDL < 100 mg/dL, and HbA1c < 8.0%.  Percentage of individuals achieving individual treatment goals and the change in absolute values for BP, LDL, and HbA1c between the intervention and usual care groups at 1 year. |
| Gary 200333 ( Fair) | HgA1c, lipids, and BP were monitored as part of the baseline assessment and the 2-year followup assessment. | No. Regimen changes were implemented under physician's orders. | Yes. NCMs provided intervention summaries to PCPs. | NR |  | Usual care: continued ongoing care from their own health care providers. They also received a quarterly newsletter on DM-related health topics.  CHW: CHWs were high school graduates attending college part time. No formal health care training prior to the study. Goal for three 45-60 minute in-home meetings a year or telephone contacts (face-to-face preferred) and as needed. CHWs monitored patient and family behavior, reinforced adherence to therapy, mobilized social support, and provided physician feedback.  NCM and CHW combined: Similar to as described. Goal for each NCM and CHW to have approximately 3 visits per year with patients and as needed. | 1. HgA1c 2. LDL cholesterol 3. HDL cholesterol 4. Triglycerides 5. SBP 6. DBP  7. Dietary risk scores 8. Physical index scores 9. BMI |
| Gary 200434 Gary 200535 Gary 200936  (Fair) | At baseline and at 24 months, HgA1c, HDL, creatinine, and urine albumin are measured. Vitals (including BP) are also measured during this time. A questionnaire is also administered. | Unclear | Yes - patient care summaries are sent to PCPs. Also, NCMs may act to coordinate between patient and PCP (e.g., prompting physician to suboptimal care patterns). | NR |  | The comparator is the "minimal intervention" group. This involves every 6-12 month phone calls by a lay health educator. The LHE also took part in a 6 week training session related to project operations, teamwork, and DM knowledge. During each phone call, the LHE reminds patients about important preventive diabetes-related health care activities. The LHE provides a summary of patient health-care utilization and general recommendations (based on ADA guidelines) to the patient's primary care provider. | HgA1c Blood pressure Lipids BMI |
| Krein 200447  (Fair) | Yes | Yes, as NP with permission of physician. | Yes, sent summary statements and consulted about medication adjustments (also gave PCP the choice to defer to the NP case manage). | No, not part of intervention. |  | All study participants were given an A&D Medical semiautomatic blood pressure monitor, home blood pressure monitoring guidelines, a lay version of the VA Diabetes Clinical Guidelines, and a periodic study newsletter. Patients in comparator group received usual care from their PCP. | A1C, BP, cholesterol and general satisfaction |
| Shea 200298 Shea 2006158 Trief 2006102 Trief 2007103 Shea 200799 Shea 2009100  Palmas 2010101  (Fair) | Home telemonitoring system had ability to upload and store blood pressures and blood glucose values.   Per Trief et al, 2006, mean number of blood glucose uploads in 1st year was 560.2, and blood pressure uploads was 184.6 | NCM communicated with PCP for any suggested medication adjustment. | Yes. Patients are recruited from primary care clinics. PCPs retain autonomy in decision making for their patients; NCMs only make suggestions based on their telemedicine patient interactions. | The home telemonitoring unit provided each patient access to their own clinical data as well as access to an educational web page for this project (created by ADA).   Patients were able to upload blood glucose and blood pressure values via their home telemonitoring unit. This information was then available to patients and NCMs. |  | Usual care  Patients in the usual care group were cared for by their PCPs. PCPs received a mailing with current guidelines for patients with DM. No other guidance from study personnel was provided to PCPs for usual care group. | Primary: -HgA1c -Blood pressure -Cost  Secondary:  -lipids -quality of life -depression |
| Wolf 2004111 (ICAN) Wolf 2007112  (Good) | No | No | Unclear | No, not part of intervention. |  | Usual care group received written educational material including the LEARN manual. Patients seen by research associate every 3 months for weight measurements and to complete questionnaires. The RA answered questions but did not assess, set goals, or have an ongoing dialogue about a participant’s diet or physical activity level. | Primary outcomes: weight and waist circumference.  Secondary measures included glycemic control  (HbA1c), lipid levels, use of prescription medications, and HRQOL. |

| **Author Year (Quality)** | **Results by Patient Health Outcomes** | **List Resource Utilization Outcomes Measured** | **Results by Resource Utilization Outcomes** | **Process Measure Outcomes Included** |
| --- | --- | --- | --- | --- |
| Babamoto 20096  (Fair) | 1. NSD within group for change in self-reported health for NCMs or standard care, but was significantly improved in CHW group (p<0.05). 2. Within group significant improvement was seen for fruit and vegetable intake for the CHW and NCM groups but not for standard care (p<0.05). The difference between groups was also significant (p<0.05). 3. There was significant improvement in exercise in CHW and standard care but not NCM (p<0.05). The difference between groups was also significant (p<0.05). 4. All groups had significant improvement in HgA1c (p<0.05). Between group differences NR.  5. There was NSD in BMI within or between groups. | 1. ED admission in previous 6 months (study period) | 1. There was NSD in ED visits among CHW and NCMs, but ED utilization increased significantly in the standard care group (p<0.05). The difference between groups was also significant (p<0.05). | 1. Never forgetting to take medications |
| Brown 201114  (Poor) | HgA1c: no significant differences between groups. Of note, individuals in the intervention group had increased HgA1c over time.  Fasting blood glucose: no significant differences between groups.   BMI: no significant differences between groups. | NR | NR | Changes in physical activity and diet Intervention attendance |
| California Medi-Cal Type 2 Diabetes Study Group 200415  Pettitt 200516: (subset analysis to determine risk of retinopathy in type 2 diabetics)  (Fair) | Although both usual care and intervention groups experienced declines in HgA1c during the study period, the reduction in the intervention group was greater at each time point (p<0.01).   Patients in the intervention group achieved their target HgA1c more often than those in usual care, regardless of HgA1c target (p<0.01).  NSD between groups for any of the secondary outcomes (weight, BMI, SBP, DBP, LDL, HDL, Cholesterol, Triglyceride). Patients in the intervention group showed statistically significant within-group decline in diastolic Bps, LDL, and total cholesterol and increase in HDL during the study period. Patients in the usual care group showed statistically significant within-group improvement in HDL during the study period.  Risk of development of retinopathy in comparator vs. intervention groups:  OR 5.35 [95% CI 1.14 –2.12], p=0.034 | NR | NR | NR |
| Ishani 201142  (Good) | Intervention group vs. usual care:  Patients with BP < 130/80 mmHg, HbA1c < 8.0%, and LDL < 100mg/dL: 21.9% vs. 10.1%, p<0.001  HbA1c < 8.0% in those with baseline HbA1c > 9.0%: 40.5% vs. 24.6%, p=0.047  LDL < 100 mg/dL in those with baseline LDL > 100 mg/dL: 40.9% vs. 27.7%, p=0.017  BP < 130/80 mmHg in those with baseline BP > 140/90mmHg: 40.6% vs. 15.9%, p<0.001 | NR | NR | NR |
| Gary 200333  (Fair) | For all comparisons between groups, usual care was the comparator. When p value not provided, assume not significant (based on Figure 1).  Reported decline in A1c for NCM group compared to comparator, but no p-value provided. P-value was <0.05 for NCM+CHW compared to comparator for decrease in HgA1c.  Reported improvement in DBP (p<0.05) for NCM+CHW, but NSD for NCM intervention alone.   Reported worsening of SBP in the NCM group vs. usual care (no p value given)   LDL appeared to worsen in all intervention groups because LDL improved in usual care compared to all intervention groups. HDL improved (increased) in NCM+CHW but not in NCM alone; no p values provided.  Reported significant improvement in triglycerides for NCM+CHW (p<0.05) but not for NCM alone.  Significant (p<0.05) within group differences included the following:  1. HgA1c decreased significantly in the NCM+CHW group. 2. LDL increased in all groups (significantly in NCM and NCM+CHW) compared to usual care because LDL declined in the usual care group. 3. SBP increased significantly in the NCM group.   There were no significant between group changes for dietary scores, physical activity index, or BMI. All intervention groups had increase in BMI compared to usual care. | NR | NR | NR |
| Gary 200434 Gary 200535 Gary 200936  (Fair) | HgA1c: no significant within group or between group differences.   NSD between group differences for blood pressure, BMI, HDL, or total cholesterol.  HDL cholesterol: significant within-group increase in HDL in favor of the intensive group (p<0.05)   Significant within-group decline in DBP for intensive intervention group (p<0.05)   When intensity of meetings with CHW/NCM was considered, those patients who had more visits with a CHW/NCM had a statistically significant decline in HgbA1c compared to the minimal intervention group (p=0.03). | ED visits Hospitalizations | At 24 months, the intensive intervention group had fewer hospitalizations compared to the minimal care group (RR 0.77, 95%CI 0.59; 1.0) but this was not statistically significant.   Those individuals with more NCM/CHW visits had significantly fewer ED visits (p<0.05, RR 0.66, 95%CI 0.43; 1.0).  Although a similar trend was seen for frequency of hospitalizations, the 95%CI crossed 1 (RR0.91, 95% CI 0.64; 1.19).  At 36 months, those who had higher frequency of CHW had significantly fewer ED visits or hospitalizations compared to minimal intervention but this result was NOT DEPENDENT on NCM intervention frequency (p<0.05, RR 0.53, 95%CI 0.36; 0.80 and 0.44, 95%CI 0.27; 0.73 respectively). | NR |
| Krein 200447  (Fair) | Absolute difference of CM-comparator (95% CI) with p values: 1) A1C: 0.13 ( 0.40 to 0.68), p=0.13 2) Change in SBP: 2 ( 4 to 8), p=0.53 3) Change in DBP 0.85 ( 2 to 4), p=0.61 4) Change in LDL: 5 ( 17 to 6), p=0.37 5) General satisfaction: 0.47 ( 0.2 to 1), p=0.04 | Hospitalizations at the VA, with VA PCP and outside the VA | Intervention vs. Comparator 1) VA Hospitalizations: 21 (19%) vs. 25 (24%) p=0.42 2) VA PCP visits: 6 (4%) 6 (4%) p=0.39 3) Received care outside VA: 24 (22%) 41 (39%) p=0.007 | Eye exams Aspirin use Statin use |
| Shea 200298 Shea 2006158 Trief 2006102 Trief 2007103 Shea 200799 Shea 2009100  Palmas 2010101  (Fair) | Shea et al, 2006 1 year results, HgbA1c:  -net adjusted reduction in HgbA1c in the intervention group was 0.18% lower than in the usual care group (p=0.006).  1 year results, HgbA1c subgroup (pts with HgbA1c >7):  -net adjusted reduction in HgbA1c was 0.32% greater in intervention vs. usual care (p=0.002) 1 year results, blood pressure:  -Net adjusted reductions for SBP and DBP were lower in the intervention group (p=0.001 for SBP and p<0.001 for DBP); BP changes in the usual care group are reported as "small." No intergroup comparisons noted. 1 year results, LDL cholesterol:  -Net adjusted differences in LDL were significant in both intervention and usual care groups (p<0.001); no intergroup comparisons noted.  Trief et al, 2006 Prospective analysis of depression as predictor of HgA1c: -baseline depressive symptoms did not predict change in HgA1c (estimate = 0.016, p>0.35); neither for comparator or intervention (p>0.911 and p>0.769 respectively).  -NSD when depression was treated as a dichotomous variable or when depression was defined by antidepressant use. Trief et al, 2007 NSD between intervention vs. usual care for change in depression (p=0.30) or "diabetes  distress" (p=0.77, p=0.98).  Shea et al, 2009 5 year results, HgbA1c Intervention group had net improvement relative to usual care (p=0.001), with net  adjusted difference of 0.29 (95% CI 0.12; 0.46).  5 year results, LDL cholesterol Intervention experienced improvement compared with usual care (p<0.001). Statistically significant differences noted in favor of intervention for years 1-4. 5 year results, blood pressure Intervention group achieved greater reductions in SBP and DBP compared to usual care (p=0.024 and p<0.001 respectively) 5 year results, mortality NSD between intervention and usual care (HR 1.01, 95% CI 0.82; 1.24) | Cost was listed as an outcome in original methods paper (Shea et al, 2002) | No formal analysis or comparisons of costs were provided.   Shea et al, 2006 did report a breakdown of costs: -total cost each home telemedicine unit was $3,425.  -Specifically, $3000 for patient station, $225 for BP cuff, $75 for cables, $125 for cart, and $110 for Glucometer. | Secondary process-of-care outcomes  -receipt of recommended DM specific health care services -compliance -education and knowledge -health beliefs  Trief et al, 2007  Changes in diabetes self-efficacy. (Definition not clearly stated).  Shea et al, 2007 Examined patient and provider satisfaction |
| Wolf 2004111 (ICAN)  Wolf 2007112  (Good) | Intervention vs. Comparator (at 12 months, 95% CI)  Primary 1) Weight: – 4.0 kg (-5.6 to -2.5) at 12 months p<0.001 for between group comparison of weight loss in favor of intervention group 2) Waist: 5.5 cm (7.4 to 3.6) vs. 1.4 cm ( 3.1 to -0.4) p<0.001 for between group comparison of decrease in waist circumference in favor of intervention group  Secondary 1) A1C values:  a) 4 months: 0.57%, 1.0 to 0.2; p=0.008 b) 8 months: 0.35%, 0.8 to 0.1; p=0.10  c) 12 months: 0.20%, 0.7 to 0.3; p=0.45 2) Total cholesterol: -8.6 mg/dl ( 22.6 to 5.5); p=0.23  3) LDL cholesterol: – 0.07 mg/dl ( 9.4 to 9.3); p=0.99 4)  4) HDL cholesterol: 0.40 mg/dl ( 1.9 to 2.7); p=0.73 5) Triglycerides: 36.0 mg/dl (–106 to 34); p=0.31 6) Quality of Life: a) Emotional 15.1 (3.4–26.8) b) Physical 10 (1.2–24.7) | Utilization defined as the number of claims during the year; hospital admissions, length of stay, and 12-month change self reported number of prescription medications taken daily. | Prescription meds: 0.8 (0.05–1.1) fewer total medications per day vs. usual care group (p=0.03).  95% CI and p-value for absolute cost difference of intervention vs. comparator:  1) Mean health care cost: -8,374 to -353 (p<0.05) 2) Mean pharmaceutical cost: -70 to $280 (NS) 3) Cost of ED visits: 862+1,488 vs. 849 + 662 (p=0.97, NS) | NR |

| **Author Year (Quality)** | **Results by Process Measure Outcomes** | **Harms Reported** | **Number Screened/ Eligible/ Enrolled** | **Number Withdrawn/ Lost to Followup/ Analyzed (overall)** | **Total Withdrawals;  Withdrawals due to Adverse Events** | **Notes** |
| --- | --- | --- | --- | --- | --- | --- |
| Babamoto 20096  (Fair) | 1. There was significant within-group improvement the percent of patients who never forgot to take medications among NCM and standard care groups (p<0.05), but not for CHWs. The difference between groups was also significant (p<0.05). | NR | 1,352 screened 354 eligible 318 randomized | They report patients who "did not complete the program" as a lump number of 129 or 41%. This number included patients who moved out of the area, withdrew, or were lost to followup. | NR | No sample size calculation |
| Brown 201114  (Poor) | Self reported changes in physical activity and fat intake improved for both intervention and comparator, but intervention did not "appear" to affect self-reported improvements beyond DSME alone (statistics NR)   Analyzed data from individuals who attended > or = 50% of DSME sessions; HgA1c improvements were larger in comparator individuals who attended this percentage of sessions compared to intervention who also attended this percentage of sessions. | NR | Screened: NR  Eligible: NR  Enrolled: 83 participants | NR | NR |  |
| California Medi-Cal Type 2 Diabetes Study Group 200415  Pettitt 200516: (subset analysis to determine risk of retinopathy in type 2 diabetics)  (Fair) | NR | The incidence of severe hypoglycemia was greater in the intervention group compared to usual care, but this different was not statistically significant (p=0.28). | Number screened: 1,597  Number eligible: 362  Number randomized: 362 | Withdrawn: NR (appears they did not keep track of withdrawals as patients only needed one followup HgA1c after baseline to be included in the analysis).  Lost to followup: 41 total (15 in intervention and 26 in usual care)  Analyzed: 317 (171 intervention, 146 usual care) | NR |  |
| Ishani 201142  (Good) | NR | NR | 729/556/556 | 7 withdrawals  10 deaths  19 randomized in error  431 analyzed: 223 intervention vs. 208 usual care, p=0.13 | No participant withdrew from the study as a result of an adverse event. |  |
| Gary 200333  (Fair) | NR | NR | Screened: 3,800 Eligible: 666 Enrolled (randomized): 186 | Authors report that roughly 84% did followup. That 84% included the 149 who completed both baseline and 2year followup visits, and the 9 who died. That leaves 28 patients (~16%) who did not followup - but why (lost, withdrawn, etc) is not discussed. | NR |  |
| Gary 200434 Gary 200535 Gary 200936  (Fair) | NR | NR | Screened: 120,000 Eligible: 2,064 Enrolled: 542 | Not reported in this way. Authors reported 18 deaths, and 36 "lost" - but why lost was not discussed. Lost vs. withdrawals also not clarified. | NR |  |
| Krein 200447  (Fair) | Dilated eye exam <12 months: 96 (87%) 84 (79%) p=0.11  NSD in aspirin use (p=0.15) NSD in statin use (p=0.20) | NR | 691 screened 246 randomized | Lost to followup: 11 Withdrawals: NR Analyzed: 209 | NR | Collected qualitative data via semistructured telephone interviews  with 40 intervention patients; 20 from each site. |
| Shea 200298 Shea 2006158 Trief 2006102 Trief 2007103 Shea 200799 Shea 2009100  Palmas 2010101  (Fair) |  | NR  Shea et al 2009 did mention that "no serious adverse events" were experienced related to the intervention. | Screened: 9,597 Eligible: 1,927 Randomized: 1,665 | Withdrawn/lost: 248 (144 intervention, 104 usual care)   Analysis of patients who completed baseline and 1-year followup examination: 1,417 (717 usual care, 700 intervention)   Analysis of all randomized subjects (baseline data carried-forward if 1- year exam not completed):  1,657 (815 usual care, 842 intervention)   \*\*Discrepancy between number randomized and number in this second analysis not explained.\*\*  Note: power calculated indicated 750 per group needed. | Total withdrawals:  \*Withdrawals vs. lost not entirely clear - these numbers extrapolated from Figure 2 of Shea, 2006.\*  Usual care withdrawals: 31 (15 due to death)  Intervention withdrawals: 160 (18 due to death)  Total withdrawals: 191 |  |
| Wolf 2004111 (ICAN)  Wolf 2007112  (Good) |  | None reported | NR/NR/147 | 29/0/147 | 29 |  |

Abbreviations: ADA=American Diabetes Association, BMI=body mass index, BP=blood pressure, CHW=community health worker, CI=confidence interval, CM=case management, DBP=diastolic blood pressure, DM=diabetes mellitus, DSME=diabetes self-management education, HRQL=health-related quality of life, HTN=hypertension, MI=myocardial infarction, ICAN= Improving Control with Activity and Nutrition Study, NCM=nurse care manager, NR=not reported, NS=not significant, NSD=no significant difference, OR=odds ratio, RD=registered dietitian, SBP=systolic blood pressure, SD=standard deviation, SES=socioeconomic status, VA=Veterans Affairs.